UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

BERNICE BROWNFIELD	)	
	)	
	)	CIVIL ACTION NO
	)	
Plaintiff,	)	2:07 cv 118 - WHA
v.	)	
	)	
GUIDANT CORPORATION, a corporation, and GUIDANT SALES CORPORATION, a corporation,	)	**DEMAND FOR JURY TRIAL**
Defendants.	)	

COMPLAINT

This is a civil action brought on behalf of the above-styled Plaintiff, who was the recipient of an implantable defibrillator including the model implanted in the Plaintiff, manufactured and distributed by Guidant Corporation and Guidant Sales Corporation. The device caused the Plaintiff to suffer personal injury and damages. This action seeks monetary damages for injuries caused by, and damages caused by, medical devices such as pacemakers and implantable defibrillators manufactured and distributed by Guidant Corporation and Guidant Sales Corporation.

PARTIES AND JURISDICTION

1. The Plaintiff, Bernice Brownfield, is an adult individual, a citizen of the State of Alabama, and resides at 3540 Jackson Road, Millbrook, Alabama 36054 in Elmore County, Alabama.

2. This action is brought by the Plaintiff to secure redress for an unlawful and negligent practice engaged in by the Defendants Guidant Corporation and Guidant

Sales Corporation (hereinafter collectively referred to as "Guidant" or "Defendant"), which are Indiana corporations with their principal place of business located in Indianapolis, Indiana. Guidant, designs, manufactures, tests, markets, distributes, and promotes and sells electronic medical devices such as pacemakers and implantable defibrillators including the models implanted in the Plaintiff.

3. At all times herein mentioned, Guidant conducted business in the State of Alabama, and within this judicial district. At all times relevant to this action, Guidant engaged in interstate commerce in this judicial district, by designing, manufacturing, testing, analyzing, distributing, recommending, merchandising, advertising, promoting, supplying and selling to distributors, and retailers for resale to physicians, hospitals, medical practitioners and the general public, certain medical devices known as "cardiac rhythm devices," including (1) pacemakers, (2) implantable cardioverter Defibrillators/Pacemakers (ICDs), (3) cardiac resynchronization therapy (CRT-P) devices, and (4) cardiac resynchronization therapy with defibrillation (CRT-D) devices.

4. Plaintiff, Bernice Brownfield, was injured and sustained damages as alleged herein, as a direct and proximate result of the conduct of the Defendants alleged herein.

5. Diversity jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1332 in that the parties are citizens of different states and the amount in controversy exceeds seventy-five thousand dollars ($75,000.00), exclusive of interest and costs.

6. Venue is proper in the Middle District of Alabama because the Defendant is a corporation that is subject to personal jurisdiction in the Middle District. In addition,

the events and omissions giving rise to the claims occurred primarily in the Middle District.

7. Personal jurisdiction and subject matter jurisdiction is appropriate in the Northern Division of the Middle District because the Plaintiff resides in the Northern Division and Defendant has done and continues to do business in the Northern Division, either directly or by agent, and have thus availed themselves of this jurisdiction.

8. Some of the Plaintiff's claims accrued in whole or in part in the Northern Division and the Plaintiff resides in Elmore County, Alabama. The Defendant has been and/or is currently engaged in business, directly or by authorized agent, in Elmore County, Alabama. Venue and jurisdiction are therefore proper. The claims of the Plaintiff herein satisfy the jurisdictional amount of this Court.

COUNT I
FACTUAL ALLEGATIONS

9. Defendant Guidant designs, develops, manufactures, distributes and markets various medical devices and other products used in the treatment of heart disease, heart failure, and peripheral vascular diseases.

10. Among Guidant's products are four types of "cardiac rhythm devices," including (1) pacemakers, (2) implantable cardioverter Defibrillators/Pacemakers (ICDs), (3) cardiac resynchronization therapy (CRT-P) devices, and (4) cardiac resynchronization therapy with defibrillation (CRT-D) devices. Guidant sells several models of each type of cardiac rhythm device, which shall, unless otherwise noted, be referred to collectively as "Defibrillators." Plaintiff has a Contak Renewal 3 implantable cardioverter Defibrillator (ICD) (Model # H170, serial # 501262) that was implanted on January 23, 2004.

11. This defibrillator was designed to be inserted under the skin, and connected to the heart with wires called "leads". The leads are in turn connected to the Defibrillators.

12. In its public disclosures, Guidant has represented that its Defibrillators are essential for saving lives. For example, Guidant's 2002 Annual Report describes them as "Lifesaving Therapy for Sudden Cardiac Death (SCD)."

13. Guidant's 2003 Annual Report boasts that, "superior engineering spurred the launch of a new implantable Defibrillator in every quarter of the past year."

14. Guidant has described its manufacturing facilities as "exceptional." Guidant's 2003 Annual Report emphasized that it has "an unrelenting focus on quality in everything" it does. Indeed, Guidant acknowledges that: "Quality is essential; lives depend on us."

15. Guidant has also publicly claimed to be an open provider of information to patients and physicians. Its 2003 Annual Report stated "information for patients, physicians and the public is available around the clock through Guidant's dedicated customer and technical service representatives, as well as its comprehensive web site (www.guidant.com)."

16. The United States Food and Drug Administration ("FDA") has approved various implantable Defibrillators designed, manufactured, and supplied by Defendants.

17. At some point prior to April, 2002 and during periods of time thereafter, Guidant learned that certain of its Defibrillators were defective and may not deliver the needed shocks to the heart of the recipient. Stated another way, the defect rendered the Defibrillators useless just when their recipients needed them to work most.

18. In April, 2002, Guidant changed the design of the Ventak Prizm Defibrillator in an effort to correct the flaw, and began to produce new Ventak Prizm Defibrillators with the modified design. In November, 2002, Guidant made a second design change to the Ventak Prizm Defibrillator, this time adding extra insulation around the component it had modified in April, 2002.

19. Guidant did not inform the FDA of its design change until August, 2003, when it disclosed the changes as part of its annual report to the FDA.

20. Guidant made no disclosure of these changes to patients or doctors and, continued to sell the Defibrillators that it had produced prior to its discovery of the defective design.

21. In a filing made with the FDA, Guidant notified the agency of design changes made to the Contak Renewal and Renewal 2 in August, 2004, to correct a short-circuiting problem in the Renewal models.

22. It has been reported that, as with the Ventak Prizm, Guidant continued to sell Renewal devices produced prior to the corrective design change well after making the corrective design changes to the Renewal models.

23. As with the Ventak Prizm, Guidant did not inform doctors or patients of the design changes made to the Contak Renewal models at the time they were made, or even at the time that Guidant informed the FDA of the changes.

24. Despite its knowledge no later than April, 2002, of the flaws in the design of its Defibrillators, and of multiple reports of Defibrillator failures since that time, including the death of at least one recipient, it was not until three years later that Defendant first alerted doctors or patients of the defects in its Defibrillators. In May,

2005, after being notified by the New York Times of the newspaper's intention to publish an article regarding the flaws in Guidant Defibrillators, Guidant initiated contact with physicians regarding short circuits in Guidant Defibrillators - one day prior to publication of the Times article.

25. According to a May 25, 2005 Press Release issued by Guidant (the "May 25 Press Release), a letter was sent on May 23, 2005 from Guidant to physicians, which identified 26 reports of Defibrillator failures, including one death. The May 25 Press Release (the actual letter sent to physicians is unavailable from Guidant's website) further states that the letter "describes a rare failure that results in the device's inability to deliver therapy."

26. The May 25 Press Release further states that the "problem is in Guidant's VENTAK PRIZM 2 DR implantable Defibrillators manufactured prior to November 2002," Devices manufactured after this date are not affected." Defendant did not state in the May 25 Press Release that Guidant had continued to sell Defibrillators with the "problem" well after April, 2002.

27. On June 3, 2005, the FDA announced that it was evaluating Guidant's handling of its Ventak Prizm Defibrillators, including the company's continued distribution of potentially flawed devices after it made a manufacturing change.

28. On June 17, 2005, at the behest of the FDA, Guidant issued a recall of the following Defibrillators made by Guidant: (1) the Contak Renewal, Model H135, as well as (2) the Contak Renewal 2, Model 155, and (3) the Ventak Prizm 2 DR Model 1861.

29. The June 17, 2005 recall was the first time Guidant had acknowledged any flaws with the Contak Renewal or Renewal 2 devices.

30. Unlike the recall on Ventak Prizm Defibrillators, which extended only to devices manufactured before April, 2002, the recall on Contak Renewal and Contak Renewal 2 devices extended to all devices manufactured up to August 26, 2004.

31. On or about June 24, 2005, issued yet another recall for still more defibrillator models, including the Contak Renewal 3 and 4, Renewal 3 and 4 A VT, and Renewal RF implantable cardioverters.

32. On July 1, 2005, the F.D.A. designated the Contak Renewal, Renewal 2 and Ventak Prizm recalls as "Class I" recalls. According to the FDA, "Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of the product will cause serious injury or death." On that same date, the FDA also designated eight other models of Guidant Defibrillators and pacemakers as "Class II" recalls, which pose a somewhat lessened but still serious risk.

33. On or around July 22, 2005, Guidant notified physicians that a programming change that it had suggested to doctors in June, 2005, might "significantly increase" the risk that a magnetic switch in the Contak Renewal, Ventak Prizm and Vitality devices would become stuck and prevent them from providing treatment.

34. On September 22, 2005, the chairman of the U.S. Senate Finance Committee notified Guidant that his committee was investigating whether the company had violated a 2003 agreement that required it to alert the government to product problems. (In June 2003, Guidant's wholly owned subsidiary, Endovascular Technologies, had pleaded guilty to federal criminal charges of failing to notify the FDA about device malfunctions and patient deaths related to stints for aortic aneurysms. As part of its plea, Guidant paid $92.4 million to settle civil and criminal charges, and signed

an agreement pledging, among other things, to notify the government about product-related problems.)

35. On September 29, 2005, the New York Times reported that two former employees of Guidant had been contacted and interviewed by criminal investigators connected with the FDA.

36. In June, 2006, Guidant announced another recall of Defibrillators, which numbered in the range of 23,000.

COUNT II
STRICT LIABILITY - FAILURE TO WARN

37. The Plaintiff hereby incorporate by reference, as if fully set forth herein, each and every count, paragraph, and allegation of this Complaint.

38. Defendants Guidant and Guidant Sales were and are engaged in the business of designing, developing, manufacturing, marketing, and selling implantable Defibrillators for ultimate use by and implantation in the bodies of heart disease patients, including the Plaintiff. The Defendants designed, developed, manufactured and sold Defibrillators to hospitals and physicians, knowing that they would thereby be sold to and implanted in heart disease patients, including the Plaintiff. As such, the Defendants are guarantors of the safety of their Defibrillators, including those implanted in the Plaintiff.

39. The Defendants knew that the aforesaid product was to be used by the user without inspection for defects therein

40. The Defendants' Defibrillators were expected to and did reach the Plaintiff without substantial change in their condition as manufactured and sold by the Defendants.

41. The Plaintiff used the product for its intended purpose.

42. The aforesaid products were unaccompanied by proper warnings of their dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. The reasonably foreseeable use of the product, i.e., implantation for use as a "cardiac rhythm device", involved substantial dangers not readily recognizable by the ordinary user of the product. The Defendants failed to warn of the known or knowable likelihood of injury including but not limited to the likelihood of short-circuiting, malfunction, and/or failure.

43. The Defendants failed to warn of the possibility of short-circuiting or other malfunction of its Defibrillators, and failed to disclose the existence of such failures, despite its knowledge of reports of such malfunctions.

44. Defibrillators manufactured by Guidant that were implanted in the Plaintiff were defective and unreasonably dangerous when implanted due to the possibility of a cardiac failure resulting from short-circuit or other defect.

45. Due to the failures described above, the defibrillator(s) implanted in the Plaintiff were in a defective condition, unreasonably dangerous in that they were and are unsafe for their intended use, and were lacking elements necessary to make them safe for their intended use.

46. As a direct and/or proximate result of the Defendants' failure to warn of this serious risk, the Plaintiff has suffered damages.

WHEREFORE, the Plaintiff respectfully request this Court enter judgment in her favor and against the Defendant for compensatory and punitive damages in a sum in excess of the jurisdictional requirement of this Court; for equitable relief and restitution; for attorneys' fees, expenses, and costs herein incurred; for interest accrued from the date

of filing; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried by a jury.

COUNT III
STRICT LIABILITY - DESIGN & MANUFACTURING DEFECTS

47. The Plaintiff hereby incorporate by reference, as if fully set forth herein, each and every count, paragraph, and allegation of this Complaint.

48. Defendants Guidant and Guidant Sales were and are engaged in the business of designing, developing, manufacturing, marketing, and selling implantable Defibrillators for ultimate use by and implantation in the bodies of heart disease patients, including the named Plaintiff and the putative class members. As such, Defendants are guarantors of the safety of those products.

49. As described above, the Guidant Defibrillators implanted in the Plaintiff were defective in design.

50. Alternatively, or additionally, the Guidant Defibrillator implanted in the Plaintiff was produced with a manufacturing defect.

51. As a result of Defendants' defective design and/or manufacturing defect, the Guidant Defibrillators were in a defective condition, unreasonably dangerous to the Plaintiff at the time Defendant sold them, and at the time they were implanted and used for their intended purposes.

52. When they manufactured and sold Guidant Defibrillators, Defendants were aware of the purpose and manner of their use. Defendants knew that the products would reach consumers without substantial and/or significant change in the condition, which Defendants sold them, and the Guidant Defibrillators in fact reached consumers

without substantial and/or significant change in condition.

53. Defibrillators manufactured by the Defendants that were implanted in the Plaintiff were defective and unreasonably dangerous when implanted, due to the possibility of a cardiac failure resulting from short-circuit or other defect.

54. Due to the failures described above, the defibrillator implanted in the Plaintiff were in a defective condition, unreasonably dangerous in that they were and are unsafe for their intended use, and were lacking every element necessary to make them safe for their intended use.

55. As a result of Defendants' defective design of the Guidant Defibrillators, the Plaintiff has suffered damages. Specifically, as a result of having Guidant's defective Defibrillators implanted, explanted, and/or exchanged and re-implanted, the Plaintiff has suffered and will continue to suffer severe physical illness and injuries; past, present, and future pain and suffering; past, present, and future mental anguish and emotional distress; permanent disfigurement and disability; past, present, and future medical and drug expenses; the hardship of recovering from those injuries; and a significantly increased risk of death or further illness and injury.

WHEREFORE, the Plaintiff respectfully requests this Court enter judgment in her favor and against the Defendants for compensatory and punitive damages in a sum in excess of the jurisdictional requirement of this Court; for attorneys' fees, expenses, and costs herein incurred; for interest accrued from the date of filing; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried by a jury.

COUNT IV
NEGLIGENCE

56. The Plaintiff hereby incorporate by reference, as if fully set forth herein, each and every count, paragraph, and allegation of this Complaint.

57. Defendants Guidant and/or Guidant Sales are the designers, manufactures, sellers, and suppliers of the implantable cardiac devices implanted in the Plaintiff.

58. As such, the Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of its Defibrillators, including a duty to assure that the devices did not short-circuit causing defibrillator recipients to suffer a risk of serious injury or death, and a duty to warn of known defects that may lead to such injury or risk of harm.

59. The Defendants breached their duty by failing to provide any meaningful warnings regarding the risk of injury or death associated with the Defibrillators. Any warnings given by the Defendants were silent as to the risk of short-circuit of Defibrillators implanted in the Plaintiff, even after the Defendants were aware of the tendency of the Defibrillators to short-circuit or otherwise malfunction, and had taken steps to correct the defect in the devices to prevent such short-circuits.

60. As such the Defendants were negligent in the design, manufacture, testing, advertising, marketing, promotion, labeling, failure to warn, and sale of their Defibrillators.

61. The Defendant knew or should have known that heart patients such as the Plaintiff would foreseeably suffer injuries as a result of Defendants' failure to exercise ordinary care as described above.

62. As the direct and proximate cause of Defendants' failure to provide

appropriate warnings for the Defibrillators, and as a result of the negligence, carelessness, other wrongdoing and actions or omissions of the Defendants, the Plaintiff had the Defibrillator implanted, explanted, and/or exchanged and re-implanted, causing the Plaintiff to suffer and to continue to suffer severe physical illness and injuries; past, present, and future pain and suffering; past, present, and future mental anguish and emotional distress; permanent disfigurement and disability; past, present, and future medical and drug expenses; the hardship of recovering from those injuries; and a significantly increased risk of death or further illness and injury.

WHEREFORE, the Plaintiff respectfully requests this Court enter judgment in her favor and against the Defendants for compensatory and punitive damages in a sum in excess of the jurisdictional requirement of this Court; for attorneys' fees, expenses, and costs herein incurred; for interest accrued from the date of filing; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried by a jury.

COUNT V
BREACH OF IMPLIED WARRANTIES

63. The Plaintiff hereby incorporate by reference, as if fully set forth herein, each and every count, paragraph, and allegation of this Complaint.

64. The Defendants are engaged in the business of designing, developing, manufacturing, marketing, and selling implantable Defibrillators for ultimate use by and implantation in the bodies of heart disease patients, including Plaintiff, by and through physicians, hospitals, and other health-care related organizations.

65. As such, the Defendants are merchants of Defibrillators.

66. By placing Guidant Defibrillators into the stream of commerce, the

Defendants impliedly warranted that the Guidant Defibrillators placed into the stream of commerce and implanted in the Plaintiff were merchantable and fit and safe for their intended use.

67. The Guidant Defibrillators placed into the stream of commerce by the Defendants that ultimately were implanted into the Plaintiff were defective in that they short-circuit and fail in their essential purpose, and are thus neither merchantable nor fit and/or safe for their ordinary or intended uses.

68. The Guidant Defibrillators placed into the stream of commerce by the Defendants that ultimately were implanted into the Plaintiff were also inadequately contained, packaged, and labeled, in that the Defendants misrepresented and/or omitted material facts regarding the safety, reliability and efficacy of the Guidant devices, and thus were neither merchantable nor fit and/or safe for their ordinary or intended uses.

69. The defects in the affected Guidant Defibrillators designed, manufactured and/or supplied and/or placed into the stream of commerce by the Defendants, were present at the time the products left the hands of the Defendants.

70. The Defendants thus breached the implied warranty of merchantability for the Guidant Defibrillators.

71. The Plaintiff were foreseeable users of the affected Guidant Devices, and as a direct and proximate result of Defendants' breach of implied warranties, the Plaintiff has suffered and will suffer severe injuries described above, for which the Defendants are liable. As a proximate result of the actionable wrongful conduct of the Defendants, the Plaintiff has suffered damages. Specifically, as a result of having Guidant's defective Defibrillators implanted, explanted, and/or exchanged and re-implanted, the Plaintiff has

suffered and will continue to suffer severe physical illness and injuries; past, present, and future pain and suffering; past, present, and future mental anguish and emotional distress; permanent disfigurement and disability; past, present, and future medical and drug expenses; the hardship of recovering from those injuries; and a significantly increased risk of death or further illness and injury.

WHEREFORE, the Plaintiff respectfully requests this Court enter judgment in her favor and against the Defendants for compensatory and punitive damages in a sum in excess of the jurisdictional requirement of this Court; for equitable relief and restitution; for attorneys' fees, expenses, and costs herein incurred; for interest accrued from the date of filing; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried by a jury.

COUNT VI
BREACH OF EXPRESS WARRANTY

72. The Plaintiff hereby incorporate by reference, as if fully set forth herein, each and every count, paragraph, and allegation of this Complaint.

73. Because Guidant deals in goods of the kind purchased by and/or implanted in the Plaintiff, i.e., Guidant Defibrillators, the Defendants, are "merchants" and "sellers", as contemplated the UCC and applicable state laws and regulations, in that they sell or contract to sell goods.

74. The Defibrillators sold by the Defendants are "goods" under the UCC and applicable state laws and regulations.

75. The Plaintiff are "buyers" in that they contracted for, purchased, and/or had implanted in their bodies, goods manufactured by the Defendants, and were the beneficiary of all express warranties attached to such goods.

76. The Defendants expressly warranted to the Plaintiff and their physicians that, among other things, the Guidant Defibrillators designed, manufactured, and supplied by the Defendants to the Plaintiff were fit and safe for their intended purpose - saving lives - and otherwise not injurious to the health and well being of the Plaintiff.

77. As detailed above, the Guidant Devices implanted in the Plaintiff failed in their essential purpose, and thus were unsafe, unmerchantable, unfit for use in the body, and otherwise injurious to the Plaintiff.

78. The Defendants breached express warranties of merchantability in the sales of affected Guidant Devices to the Plaintiff in that their Defibrillators either manifested a failure, and/or were defective and thus not fit for their ordinary purposes.

79. As a direct and proximate result of Defendants' breach of their express warranties as described herein, the Plaintiff did in fact suffer and will continue to suffer severe physical injuries as set forth above.

80. Since the essential purpose of the warranty has failed, the Plaintiff are entitled to incidental and consequential damages, as appropriate, under the UCC and applicable state laws and regulations.

81. The Plaintiff has suffered and will suffer severe injuries described above, for which the Defendants are liable. As a proximate result of the actionable wrongful conduct of the Defendants, the Plaintiff has suffered damages. Specifically, as a result of having Guidant's defective Defibrillator implanted, explanted, and/or exchanged and re-implanted, the Plaintiff has suffered and will continue to suffer severe physical illness and injuries; past, present, and future pain and suffering; past, present, and future mental anguish and emotional distress; permanent disfigurement and disability; past, present, and

future medical and drug expenses; the hardship of recovering from those injuries; and a significantly increased risk of death or further illness and injury.

WHEREFORE, the Plaintiff respectfully requests this Court enter judgment in her favor and against the Defendants for compensatory and punitive damages in a sum in excess of the jurisdictional requirement of this Court; for equitable relief and restitution; for attorneys' fees, expenses, and costs herein incurred; for interest accrued from the date of filing; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried by a jury.

COUNT VI
FRAUD

82. The Plaintiff hereby incorporate by reference, as if fully set forth herein, each and every count, paragraph, and allegation of this Complaint.

83. The Defendants directly and indirectly, made material misrepresentations, or failed to disclose material facts, to the Plaintiff and their physicians concerning problems with the Guidant Defibrillators, and specifically with short-circuits while charging to deliver necessary shocks.

84. These material misrepresentations and omissions were made by Defendants to the Plaintiff and to the Plaintiff physicians both before and after the Plaintiff were implanted – and, where applicable, re-implanted – with Guidant devices.

85. The Defendants, through their experience, were in a position of superiority over the Plaintiff, and even over the Plaintiff physicians, with respect to knowledge and information concerning the tendency of Guidant Defibrillators to short-circuit or otherwise fail, and the incidence of such failures and malfunctions.

86. The Defendants had a duty to disclose these facts to the Plaintiff, but failed to

do so.

87. The material misrepresentations and omissions were, or should, have been known by Defendants to be false when made.

88. The Defendants intended, or could reasonably have foreseen or expected, that these material misrepresentations and omissions would influence the Plaintiff and their implanting physicians in their decisions to implant Guidant Defibrillators.

89. The Plaintiff and their physicians in fact relied, to the Plaintiff detriment and injury, upon the false statements of fact and material omissions made by the Defendants, reasonably and justifiably, and were the beneficiary of all express warranties attached to such goods.

90. As a direct and proximate cause of defendant's conduct, the Plaintiff has suffered and will continue to suffer from sever injuries, as set forth above.

91. The Plaintiff has suffered and will suffer severe injuries described above, for which the Defendants are liable. As a proximate result of the actionable wrongful conduct of the Defendants, the Plaintiff has suffered damages. Specifically, as a result of having Guidant's defective Defibrillators implanted, explanted, and/or exchanged and re-implanted, the Plaintiff has suffered and will continue to suffer severe physical illness and injuries; past, present, and future pain and suffering; past, present, and future mental anguish and emotional distress; permanent disfigurement and disability; past, present, and future medical and drug expenses; the hardship of recovering from those injuries; and a significantly increased risk of death or further illness and injury.

WHEREFORE, the Plaintiff respectfully requests this Court enter judgment in her favor and against the Defendants for compensatory and punitive damages in a sum in

excess of the jurisdictional requirement of this Court; for equitable relief and restitution; for attorneys' fees, expenses, and costs herein incurred; for interest accrued from the date of filing; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried by a jury.

COUNT VII
FRAUD BY CONCEALMENT

92. The Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every count, paragraph, and allegation of this Complaint.

93. At all times relevant to this action, the Defendants had the duty and obligation to disclose to the Plaintiff and to their physicians, the true facts concerning the Guidant Defibrillators, specifically that said product was dangerous and defective and how likely it was to cause serious injuries and/or death.

94. The Defendants made affirmative representations as set forth herein to the Plaintiff, their physicians, and the general public, while concealing the following material facts:

a. That the implanted Guidant Defibrillators were defective, such that the affected Guidant Devices would short circuit and fail to function as intended;

b. That the Defendants knew of numerous failures of the Guidant Defibrillators, yet failed to disclose such knowledge.

c. That the Defendants had altered the design of similar devices and had failed to disclose such alterations, thus foreclosing the opportunity to inquire as to changes in the implanted Defibrillator;

d. That the Defendants had altered the design of the implanted Defibrillators

following implantation in the Plaintiff;

e. That the affected Guidant Defibrillators were inherently dangerous; and

f. That the explanted Guidant device, where applicable, would be provided immediately to Guidant for "evaluation."

95. At all times relevant to this action, the Defendants had the duty and obligation to disclose the foregoing facts concerning the Guidant Defibrillators to the Plaintiff and to their physicians.

96. At all times relevant to this action, the Defendants intentionally, willfully, and maliciously concealed or suppressed the facts set forth herein from the Plaintiff and from the Plaintiff physicians, with the intent to defraud as herein alleged.

97. At all times herein mentioned, neither the Plaintiff nor their physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, they would not have utilized the product.

98. As a result of the concealment or suppression of the facts set forth above, the Plaintiff suffered injuries as set forth herein.

99. By committing the actions and omissions herein alleged, the Defendants acted with oppression, fraud, and malice, and the Plaintiff are therefore entitled to punitive damages in an amount reasonably related to the Plaintiff actual damages, and to the Defendants' wealth, and in an amount sufficiently large to be an example to others, and to punish and deter the Defendants and others like the Defendants from engaging in similar conduct in the future.

100. That at all times relevant to this action, the Defendants intentionally, willfully, and maliciously concealed or suppressed the facts set forth herein from the

Plaintiff and from the Plaintiff physicians, with the intent to defraud the Plaintiff as herein alleged.

101. At all times herein mentioned, neither the Plaintiff nor their physicians were aware, nor in the exercise of reasonable and/or ordinary care or diligence did they know or would they have known, of the facts set forth herein, and had they been aware of the facts misrepresented and/or concealed by the Defendants, they would not have acted as they did; that is, the Plaintiff physicians would not implanted Guidant Defibrillators in the Plaintiff, and the Plaintiff would not have Guidant Defibrillators implanted in them.

102. As a result of the concealment or suppression of the facts set forth above, the Plaintiff suffered injuries and damages as set forth herein.

103. In committing the actions herein alleged, the Defendants acted with oppression, fraud, and malice, and the Plaintiff are therefore entitled to punitive damages in an amount reasonably related to the Plaintiff actual damages, and to the Defendant's wealth, and in an amount sufficiently large to be an example to others, and to punish and deter the Defendants and others like the Defendants from engaging in similar conduct in the future.

104. The Plaintiff has suffered and will suffer severe injuries described above, for which the Defendants are liable. As a proximate result of the actionable wrongful conduct of the Defendants the Plaintiff has suffered damages. Specifically, as a result of having Guidant's defective Defibrillator implanted, explanted, and/or exchanged and re-implanted, the Plaintiff has suffered and will continue to suffer severe physical illness and injuries; past, present, and future pain and suffering; past, present, and future mental anguish and emotional distress; permanent disfigurement and disability; past, present, and

future medical and drug expenses; the hardship of recovering from those injuries; and a significantly increased risk of death or further illness and injury.

WHEREFORE, the Plaintiff respectfully requests this Court enter judgment in her favor and against the Defendants for compensatory and punitive damages in a sum in excess of the jurisdictional requirement of this Court; for equitable relief and restitution; for attorneys' fees, expenses, and costs herein incurred; for interest accrued from the date of filing; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried by a jury.

COUNT VIII
UNJUST ENRICHMENT AS TO DEFENDANTS

105. The Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein, and further allege as follows:

106. As a direct, proximate, and foreseeable result of the Defendants' acts and otherwise wrongful conduct, the Plaintiff was gravely harmed. The Defendants profited and benefited from the sale of the medical devices described herein, even as they injured the Plaintiff.

107. The Defendants have voluntarily accepted and retained these profits and benefits, derived from consumers, including the Plaintiff, with full knowledge and awareness that, as a result of the Defendants' unconscionable and intentional wrongdoing, consumers, including the Plaintiff, were not receiving products of the quality, nature, fitness, or value that had been represented by the Defendants or that reasonable consumers expected. The Plaintiff purchased medical devices that they expected would improve their health, and instead found their health adversely affected, impaired, and/or destroyed by those devices.

108. By virtue of the conscious wrongdoing alleged in this Complaint, the Defendants have been unjustly enriched at the expense of the Plaintiff, who are entitled to equitable relief and restitution, and who hereby seek the disgorgement and restitution of the Defendants' wrongful profits, revenue, and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendant's unjust enrichment.

WHEREFORE, the Plaintiff respectfully requests this Court enter judgment in her favor and against the Defendants for compensatory and punitive damages in a sum in excess of the jurisdictional requirement of this Court; for equitable relief and restitution; for attorneys' fees, expenses, and costs herein incurred; for interest accrued from the date of filing; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried by a jury.

DAMAGES

109. Upon the trial of this case, it will be shown that the Plaintiff was caused to sustain injuries and damages as a direct and proximate result of Defendants' conduct and Plaintiff will respectfully request the Court and jury to determine the amount of loss Plaintiff has suffered and incurred, in the past and in the future, not only from a financial standpoint, but also in terms of good faith, freedom from pain and worry.

110. At all times relevant hereto, Defendants actually knew of the defective nature of their product as herein set forth and continued to design, manufacture, market, distribute and sell their product so as to maximize sales and profits at the expense of the public health and safety in conscious disregard of the foreseeable harm caused by these product. Defendants' conduct exhibits such an entire want of care as to establish that

their actions were a result of fraud, ill will, recklessness, gross negligence, or willful or intentional disregard of the Plaintiff's individual rights. The Plaintiff, therefore, is entitled to punitive damages from the Defendants.

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that the Defendants be cited to appear and answer herein; that upon final trial herein, Plaintiff recover damages as set forth above from Defendants, including costs of Court, pre-judgment and post-judgment interest at the legal rates; and that Plaintiff be granted such other and further relief, both general and special, at law and in equity, to which the Plaintiff is justly entitled under the facts and attending circumstances.

DEMAND FOR JURY TRIAL

The Plaintiff demands a trial by struck jury.

Kathryn S. Harrington

Kathryn S. Harrington(ASB-7984-M73K)
Attorney for Plaintiff
Bar Code No.: SUM002

OF COUNSEL:
Hollis & Wright P.C.
Financial Center
505 North 20th Street, Suite 1500
Birmingham, Alabama 35203
(205) 324-3600

REQUEST FOR CERTIFIED MAIL SERVICE BY CLERK

Attorney for Plaintiff hereby requests that the clerk serve the following defendants by certified mail, return receipt requested.

Kathryn Harrington
OF COUNSEL

PLEASE SERVE THE FOLLOWING DEFENDANT VIA CERTIFIED MAIL:

Guidant Corporation
c/o CSC Lawyers Incorporating SVC, Inc.
150 South Perry Street
Montgomery, Alabama 36104

Guidant Sales Corporation
c/o CSC Lawyers Incorporating SVC, Inc.
150 South Perry Street
Montgomery, Alabama 36104